DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 8, 2015

Xeridiem (formerly Mri)
Jesus Valencia
RA Specialist
4700 S. Overland Drive
Tucson, AZ 85714

Re: K142075
Trade/Device Name: Bi-Funnel Gastrostomy Feeding Tube and Tri-Funnel Gastrostomy Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: December 11, 2014
Received: December 12, 2014

Dear Jesus Valencia,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142075

Device Name
Bi-Funnel Gastrostomy Feeding Tube and Tri-Funnel Gastrostomy Feeding Tube

Indications for Use *(Describe)*
The G-Tube is indicated for placement in adult populations that require enteral feeding, medication administration or gastric decompression through an established gastrointestinal stoma tract.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

(End of Section)

510(k) Summary

As required by 21 CFR 807.92, this "510(k) Summary" provides a basis for the substantial equivalence determination of the device listed below.

General Information

Date Prepared: January 6th, 2015

510(k) Submitter:
Xeridiem
4700 S. Overland Dr.
Tucson, AZ 85714
Contact: Jesus Valencia, RA Specialist
(520) 882-7794 ext. 135
jvalencia@xeridiem.com

510(k) Correspondent: Same as above

Device Information

Trade Name:	Bi-Funnel Gastrostomy Feeding Tube and Tri-Funnel Gastrostomy Feeding Tube
Common Name:	Balloon Gastrostomy Feeding Tube
Classification Name:	Gastrointestinal Tubes and Accessories [21 CFR 876.5980, Product Code PIF]
Classification Panel:	Gastroenterology/Urology
Class:	Class II

Predicate Device Information

Trade Name:	Flow-Thru (Compat®) Balloon Replacement Gastrostomy Tubes
Common Name:	Balloon Gastrostomy Feeding Tube
Classification Name:	Tubes, gastrointestinal (and accessories) [21 CFR 876.5980, Product Code KNT]
Classification Panel:	Gastroenterology/Urology
Class:	Class II
510(k) Number:	K885339

Device Description

The Gastrostomy Feeding Tube (G-Tube) consists of two product versions (models): a Bi-Funnel G-Tube and a Tri-Funnel G-Tube. Each G-Tube version is offered in varying shaft French (FR) sizes and balloon sizes. Both versions are offered in the same functional length. The overall difference between the Bi-Funnel and Tri-Funnel G-Tube is that the Tri-Funnel G-Tube allows for simultaneous delivery of feeding solutions and medications while the Bi-Funnel G-Tube allows for delivery of either feeding solutions or medications at a time. The table below summarizes the device offerings for the Bi-Funnel and Tri-Funnel G-Tubes:

Table 5.1 – Proposed Device Offerings

Model P/N:	Device Description	French Size Offerings (FR)	Balloon Recommended Fill Volume (mL)	Functional Length (cm)
70-0047	**Bi-Funnel Gastrostomy Feeding Tube**	12	5	10
		14		
		16		
		18	20	
		20		
		22		
		24		
70-0048	**Tri-Funnel Gastrostomy Feeding Tube**	12	5	10
		14		
		16		
		18	20	
		20		
		22		
		24		

Both Bi-Funnel and Tri-Funnel G-Tubes consist of a silicone funnel, shaft, adjustable external bolster and balloon. The funnel for the Bi-Funnel G-Tube has two ports: one port houses the balloon inflation valve which allows for balloon inflation and deflation, and the other port houses the male ENFit* connector (also known as PG Lock* connector) which allows for delivery of feeding solutions and medication. The funnel for the Tri-Funnel G-Tube has three ports: one port houses the balloon inflation valve, the center port houses the male ENFit connector which allows for delivery of feeding solutions, and the last (side) port houses another male ENFit connector which allows for delivery of medications. Attached to the ENFit connectors are a tether and a cap. The cap is intended to cover the ENFit connector when the device is not in use and the tether is intended to secure the cap to the connector when the device is in use. The same ENFit connector, tether and cap components are used for both Bi-Funnel and Tri-Funnel G-Tubes. The remaining components (shaft, adjustable bolster and balloon) are commonly shared for the Bi-Funnel and Tri-Funnel G-tubes and identical in both versions.

- ***Note:** The term "PG Lock" was the generic name used to describe the enteral connectors attached to the proposed device before these had an industry trade name. After commencing the design and development project for the proposed device, the Global Enteral Device Supplier Association (GEDSA) settled on an industry trade name for the enteral connectors and termed these connectors "ENFit". Within the body of this submission and within the supporting documentation, both "PG Lock" and "ENFit" connectors are used interchangeably; however, both terms refer to the same enteral connectors.*

In use, the distal end of the G-Tube is inserted through a gastrointestinal stoma tract and into the stomach. Once the device is inside the stomach, a male luer slip or luer lock syringe is connected to the balloon inflation valve and the balloon is inflated with sterile or distilled water to the recommended fill volume printed on the balloon inflation port. Then, the G-Tube is withdrawn until the balloon stops against the inner stomach wall and lastly the external bolster adjusted flush against the abdomen by sliding down the bolster along the shaft of the G-Tube. The shaft is printed with the rated shaft French size and graduation marks as a reference for identifying the diameter and length of the stoma tract. Once secured in place, the G-Tube will serve as a channel for administering nutrients and medication into the stomach and for gastric decompression. Enteral administration sets and syringes incorporating female ENFit connectors will be connected to the male ENFit connectors on the G-Tubes for delivering feeding solutions, medications, and for tube flushing. The male ENFit connection system was designed with the purpose of preventing unwanted misconnections with non-enteral connectors (i.e., luers delivering I.V. fluids). When device replacement is deemed necessary, the balloon is deflated and the G-Tube is pulled out of the stoma tract. The G-Tube is then replaced as previously described above. A more detailed device description with drawings is included in Section 11 of this 510(k).

Intended Use

The Gastrostomy Feeding Tube (G-Tube) is intended to provide enteral feeding, medication administration and gastric decompression.

Indications for Use

The G-Tube is indicated for placement in adult populations that require enteral feeding, medication administration or gastric decompression through an established gastrointestinal stoma tract.

Technological Characteristics

The device comparison table below provides a general summary of the technological characteristics of the Gastrostomy Feeding Tube (proposed) device compared to the predicate device.

Table 5.2 – Device Comparison Table

	Gastrostomy Feeding Tube (Proposed device)	**Flow-Thru (Compat®) Balloon Replacement Gastrostomy Tubes** (Predicate Device) - *K885339*
FDA Class	Same as K885339	Class II
FDA Product Code	PIF	KNT
FDA Regulation	Same as K885339	876.5980 – Tubes, gastrointestinal (and accessories)
510k #	N/A	K885339
Indications for Use	The G-Tube is indicated for placement in adult populations that require enteral feeding, medication administration or gastric decompression through an established gastrointestinal stoma tract.	The Compat® Replacement Gastrostomy Tube is used as a replacement for surgically, laparoscopically or endoscopically placed gastrostomy tubes when an established, well-healed and mature tract (i.e. stoma tract) between the stomach and external body surface exists. The device delivers enteral formula and medications directly into the stomach and is intended for single patient use.
User Population	Same as K885339	Adult
Operating principle	Same as K885339	Device tip enters though the stoma tract and into the stomach, then the device is secured in place by inflating the balloon and adjusting the external bolster. Once secured in place, the device serves as a channel for administering nutrients and medication into the stomach and for gastric decompression
Single Patient Use	Same as K885339	Yes
Sterile	Same as K885339	Yes (ETO)
Shaft	Same as K885339	Silicone 70D
External Bolster	Same as K885339	Silicone 40D
Balloon	Same as K885339	Silicone 24D
Funnel	Same material as K885339 with slight difference in profiles	Silicone 60D
Radiopaque Marker	Same as K885339	Barium Sulfate
Connectors	ABS (Connectors/Caps) & LLDPE (Tether)	Polyvinyl Chloride Connectors & Polycarbonate Barbed Adaptor
Balloon Inflation Valve	Same material types as K885339 with slight difference in profiles	Thermoplastic inflation valve
Product Offerings	12 – 24 French Sizes (Shaft) 0 – 10 cm (Functional Length) 5 & 20 mL (Balloon Recommended Fill Volume)	14 – 24 French Sizes (Shaft) 0 – 10 cm (Functional Length) 5 & 15 mL (Balloon Recommended Fill Volume)
Packaging	Same as K885339	Poly/Tyvek Chevron Pouch (1 unit and two labeling inserts inside pouch)
Kit Components	Same as K885339	None

Performance Characteristics

Nonclinical bench testing was conducted for supporting substantial equivalence between the proposed and predicate devices. The bench tests addressed device performance characteristics such as:

- ASTM F2528 testing
  - Flow rate
  - Balloon burst volume
  - Balloon volume maintenance
  - Balloon concentricity
  - Balloon size over shaft size
  - Balloon integrity in water
  - Balloon integrity in simulated gastric fluid
- ENFit performance testing
  - Falling drop test
  - Stress cracking
  - Resistance to axial load
  - Resistance to separation from unscrewing
  - Resistance to overriding
  - Disconnection by unscrewing
- Tensile testing
- Leak testing
- Simulated use (human factors)
- Shelf life testing
- Sterilization
- Packaging validation
- Biocompatibility
- Enteral Connector Misconnection Assessment
- Enteral Connector Risk Management Report
- Human Factors Validation Study
- ENFit Misconnection data with FMEA

A more detailed description of the performance testing is included in Section 18 of this 510(k). In conclusion, the proposed device performed equivalent to or better than the predicate device.

Device Comparison

As outlined in Table 5.2, the proposed device is substantially equivalent to the legally marketed predicate device. Specifically, the proposed device have has the same intended use, in as far as that both are used for administration of enteral nutrition and gastric decompression, and similar indications, technological characteristics, and principles of operation as the previously cleared predicate device. A substantial equivalence device comparison table comparing the similarities and differences between the proposed device and its predicate is provided in Table 5.2 above. The proposed device differs from the predicate device in certain funnel and connector design features which are required to reduce the likelihood of enteral misconnections and the profile of the funnel and connector ports. The minor differences identified in the technological characteristics do not raise new questions of safety or efficacy. Performance (bench) testing demonstrates that the proposed device is as safe and effective as its predicate device.

Substantial Equivalence – Comparison to Predicate Device

In order to support substantial equivalence of the proposed device to its predicate, the following are provided among the information and summary tables included in this 510(k) submission: 1.) device description, 2.) indications for use, 3.) device comparison tables, 4.) material information, 5.) nonclinical (bench) test results, and 6.) product labeling. In particular, nonclinical test results demonstrate that there were no differences that are critical to the intended use of the proposed device or that affect the safety and effectiveness of the proposed device when used as labeled.

The proposed and predicate devices have the same intended use, in as far as that both are used for administration of enteral nutrition and gastric decompression, and similar indications, technological characteristics and principles of operation. The minor differences in technological characteristics have been identified and do not present any new issues of safety or effectiveness. Thus, the Gastrostomy Feeding Tube is substantially equivalent to the Flow-Thru (Compat®) Balloon Replacement Gastrostomy Tubes (K885339).

(End of Section)